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January 20, 2012

VIA ECF

Honorable Tonianne J. Bongiovanni, U.S.M.J
United States District Court
District of New Jersey
Clarkson S. Fisher Federal Bldg. & U.S. Courthouse
402 East State Street
Room 6052
Trenton, NJ 08608

Re: AstraZeneca vs. Hanmi, Civil Action No.: 11-760 (JAP) (TJB)

Dear Judge Bongiovanni:

This firm, along with Sughrue Mion, PLLC, represents the Hanmi Defendants ("Hanmi") in the above-referenced matter. As instructed by the Court in its January 17, 2012 correspondence, Hanmi respectfully submits this letter in response and opposition to AstraZeneca's January 13, 2011 request for an order striking certain portions of Hanmi's Supplemental Non-infringement and Invalidity Contentions ("supplemental contentions").

Hanmi supplemented its initial contentions to address the claims belatedly added to the case by AstraZeneca. AstraZeneca does not take issue with those supplementations expressly directed to claims 3, 5 and 10, but rather, the revisions to Hanmi's original contentions which were necessitated by the Court's order regarding claims 3, 5 and 10 and/or which conformed them to the current case record, such as by incorporating by reference summary judgment and *Markman* briefing -- none of which can be a surprise to AstraZeneca. Particularly in light of AstraZeneca's motion to add claims 3, 5 and 10 (D.I. 81- 82), and the Court's Order granting the same (D.I. 139), Hanmi's supplementations were made pursuant to the Court's Order and are entirely proper. As a result, AstraZeneca's letter request to strike should be denied and AstraZeneca should be ordered to immediately serve any outstanding responses to Hanmi's

supplementations, which were due on January 13, 2011 but withheld by AstraZeneca in violation of the Court's Order granting supplemental contention exchange dates (D.I. 145).

Argument

AstraZeneca's assertion that Hanmi was required to seek leave to supplement its contentions is incorrect and should be rejected for a number of reasons.

First, Hanmi's supplemental contentions served on December 9, 2011 are entirely proper. Exhibit 1 is a redlined version of the supplemental contentions, showing that about six pages of text were added to Hanmi's original detailed set of contentions (146 pages) served May 25, 2011 (D.I. 87-1). Hanmi's supplementations were either necessitated by the new claims added to the case, or premised on Hanmi's previously asserted May 25, 2011 positions and directed to conforming Hanmi's contentions to the case record. [1] AstraZeneca primarily complains about the portions where Hanmi updated its positions to be in conformity with the up-to-date record, for example, incorporation by reference of Hanmi's summary judgment motions.[2] These portions were revised merely to conform to the record and do not contain any "new contentions."

In fact, as to lack of enablement of hydrated forms, Hanmi's May 25, 2011 invalidity contentions provided specifically that:

> Based on the lack of direction or guidance presented about how to obtain crystalline esomeprazole strontium tetrahydrate, the absence of working examples, the lack of prior art regarding pharmaceutically acceptable strontium salts in crystalline form, the unpredictability of crystalline salt formation, and the breadth of the claims relative to the disclosure, claims 1-2, 4 and 6-7 as asserted against Hanmi are invalid under Section 112, first paragraph, for failure to comply

[1] Indeed, Hanmi explained this to AstraZeneca by cover letter when it served its Supplemental Contentions:

> Per the Court's order filed on December 2, 2011, enclosed are Hanmi's First Amended Non-Infringement and Invalidity Contentions in response to AstraZeneca's November 21, 2011 Amended Disclosure of Asserted Claims. Where we revisited a defense because it applied to claims 3, 5 or 10, we updated the contentions as appropriate, including conforming them to subsequent developments in the case, and made a few clarifications. Nothing in our contentions will come as a surprise.

(Exhibit 2, 12/9/11 Scherling to Rothman).

[2] Nothing else identified by AstraZeneca can be considered "new." (*See* D.I. 182, Ex. A at pp. 3, 15, 72, 75, 78, 79, 86, 92, 93, 98, 102 (identifying incorporations by reference of Hanmi's summary judgment motions, clarifying comments, specific citations in previously identified prior art, etc.)

> with the enablement requirement. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

D.I. 87-1 at 70. As to lack of written description, Hanmi's May 25, 2011 contentions included the specific contention that:

> To the extent AstraZeneca asserts that any of claims 1, 2, 4, 6 and 7 encompass and read on Hanmi's proposed products containing a crystalline strontium salt of esomeprazole, in tetrahydrate form, claims 1, 2, 4, 6 and 7 are invalid for failure to satisfy the written description requirement of 35 U.S.C. 112, first paragraph.

D.I. 87-1 at 73.

Following its May 25, 2011 contentions, -- and based on those very contentions -- Hanmi filed Summary Judgment Motions 1-5 on October 11, 2011 (D.I. 97-D.I. 119) ("Motions 1-5" or "summary judgment motions"). Refusing to timely oppose each of Hanmi's motions, AstraZeneca requested that the Court direct Hanmi to seek leave to amend its contentions on the grounds that some aspects of Hanmi's summary judgment motions were allegedly based on legal theories (*e.g.*, lack of written description of hydrates) not previously disclosed in its contentions. (D.I. 124.) Hanmi opposed, citing support in its May 25 contentions for each of the questioned summary judgment motions (D.I. 126), and the Court indeed did not require Hanmi to amend its contentions as AstraZeneca requested, but rather ordered completion of briefing. The present motion is little more than a re-argument of the same position AstraZeneca put forth months ago, which this Court has already denied.

Second, the Court ordered and permitted Hanmi to supplement its contentions when it allowed AstraZeneca to add claims 3, 5 and 10 (D.I. 138). In light of AstraZeneca's belated assertion of new claims, the Court explained in its November 14, 2011 Memorandum Opinion that Hanmi would need to "invest additional resources in evaluating claims 3, 5 and 10 of the '504 patent ***and that the inclusion of these claims in this matter will likely also require Hanmi to adjust their case strategy going forward.***" (D.I. 138, p. 14, emphasis added). Based on the Court-ordered schedule governing the exchange of supplemental contentions responsive to AstraZeneca's assertion of new claims (D.I. 142), Hanmi responded specifically with its defenses pertaining to new claims 3, 5 and 10, as well as any other claims (where its positions required adjustment in view of the new claims). Hanmi also updated its contentions to reflect the record developed as of that point in the case, including incorporating by reference of Hanmi's Motions 1-5 and *Markman* briefing. A total of about six pages were added. (*See* Ex. 1).

Third, contrary to AstraZeneca's suggestion, the disclosure obligations of the Local Patent Rules do not function as limitations on any further case development. Contentions do not function as a "straitjacket in which litigants are locked from the moment their contentions are served" at the start of the case prior to any fact or expert discovery or claim construction. (D.I. 138, p. 8, citing *Comcast Cable Communs. Corp. v. Finisar Corp.*, 2007 WL 716131, at *2 (N.D. Cal. March 2, 2007)). As explained by the Court, the Local Patent Rules "exist to further the goal of full, timely discovery and provide all parties with adequate notice and information

with which to litigate their cases." (D.I. 138, p. 8, citing *Computer Accelerations Corp. v. Microsoft Corp.*, 503 F. Supp.2d 819, 822 (E.D. Tex. 2007). The function of the disclosure obligations is to provide notice. Rigid preclusion of case development is illogical and would contravene the liberal standards for case development under the Federal Rules, especially here where the portions of Hanmi's contentions AstraZeneca seeks to have stricken have been fully briefed by the parties, in the summary judgment motions. AstraZeneca can hardly be said to have been deprived of "notice" where it fully responded to all five summary judgment motions and Hanmi's *Markman* brief, provided declaration and documentary evidence in support, and at no time stated it was unable to respond based on Hanmi's not having provided to it a greater level of detail in its May 25 contentions. Moreover, any suggestion that a defendant in a Hatch-Waxman litigation must be prepared to have developed its full case in its initial contentions in the same level of exacting detail ordinarily reached at the time of a final pre-trial order is simply wrong.

Updating and further narrowing of the parties' respective positions is expected as any case proceeds. In fact, Hanmi expects to supplement its contentions as the case proceeds towards trial,[3] and would expect AstraZeneca to do the same (as it too has expanded and supplemented its positions over the course of discovery and various rounds of briefing). To the extent a preclusive effect is embodied by the Rules, it is to avoid shifts and additions to the case at a point in time where an opposing party cannot respond or there would be some prejudice. Indeed, this principle is evidenced by the Court's Order allowing AstraZeneca to assert new claims and alter its infringement contentions mid-stream -- as a result requiring Hanmi to alter its case strategy.

Fourth, AstraZeneca's presently narrow view of the Rules governing disclosure is plainly inconsistent with the broad and liberal standard it urged in seeking amendment of its Disclosure of Asserted Claims. Similarly, in the present *Markman* briefing schedule, AstraZeneca articulated for the first time in its opening submissions what are new and previously undisclosed theories of claim construction (*see, e.g.*, Hanmi's concurrently filed letter opposition to AstraZeneca's request to strike portions of Hanmi's responsive *Markman* submissions), having no basis whatsoever in AstraZeneca's Infringement and Responsive Invalidity Contentions or the Joint Claim Construction and Prehearing Statement (D.I. 92, 92-1). AstraZeneca should not be permitted to benefit both from a liberal interpretation of the rules when applied to its own disclosures yet a narrow interpretation of the same rules when applied to Hanmi's disclosures. AstraZeneca's "double standard" approach to the Rules should be rejected.[4]

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[3] Of course, if the occasion for future supplementation is, unlike here, not presented in the context of existing permission via an order of the Court to supplement, Hanmi will seek leave as appropriate pursuant to the Local Rules.

[4] AstraZeneca's claims that Hanmi refused to meet and confer on the propriety of Hanmi's Supplemental Contentions are likewise misplaced. On December 20, 2011 AstraZeneca wrote to Hanmi regarding alleged "new" claim construction issues and indicating "[t]o the extent Hanmi purported to amend their contentions with regard to claims other than 3, 5 and 10 of the '504 patent, those amendments are not properly part of this case" and requested a meet and confer.

Conclusion

AstraZeneca has failed to demonstrate Hanmi's supplemental contentions were improper under the rules[5] or that AstraZeneca was in any way unfairly prejudiced because of Hanmi's contentions including conforming revisions. Accordingly, Hanmi respectfully requests that AstraZeneca's motion to strike Hanmi's supplemental contentions be denied, and that the Court order AstraZeneca to provide any responsive supplemental contentions AstraZeneca refused to include in its January 13, 2011 paper forthwith.

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Respectfully,

/s/ Allyn Z. Lite

Allyn Z. Lite

AZL:emp

cc: Hon. Joel A. Pisano, U.S.D.J. (via ECF)
All Counsel of Record (via ECF)

(Ex. 3, 12/20/11 Rothman to Scherling). A meet and confer was scheduled and took place on December 27, and the record reveals no continued allegations of "new" contentions or a motion to strike until January 12, 2012, the eve of the date for AstraZeneca to provide its responsive contentions. (Ex. 3, 12/21/11-1/3/12 Rothman/Scherling correspondence and 1/12/12 Rothman/Dzwonczyk correspondence.)

[5] *Hoffman-LaRoche Inc. v. Apotex.*, C.A. No. 07-4417, D.I. 397 (D.N.J. Dec. 29, 2011), relied upon by AstraZeneca in support of the present motion, is irrelevant both factually and legally.